

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-06 EUR-12 EA-09 NEA-10 ISO-00 OES-05 /049 R

DRAFTED BY: DHEW/FDA:JRWEINROTH, M.D.:AMS

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DHEW/OIH:MACODDING

EUR/NE:KHSIRLEY (INFO)

NEA/ARN:MHMAUGHAN (INFO)

NEA/ARP:JPLYLE (INFO)

EA/ANP:MMICHAUD (INFO)

NEA/EGY:GBEYER (INFO)

NEA/ARN:TJCAROLAN (INFO)

AF/S:FBCRUMP (INFO)

EA/PRCM:OVARMSTRONG

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R 310339Z JAN 76

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY BRUSSELS

AMEMBASSY CAIRO

USINT BAGHDAD

AMEMBASSY AMMAN

AMEMBASSY KUWAIT

AMEMBASSY PRETORIA

AMCONSUL CAPE TOWN

AMCONSUL HONG KONG

UNCLAS STATE 024872

FOR EMBASSY CAPE TOWN

E.O. 11652: NA

TAGS: OGEN, ETRD, TBIO, AS, BE, EG, HK, IZ, JO KU, SF

SUBJECT: FDA ADVISORY - ADVERSE REACTIONS TO VETERINARY DRUG
(VOLUNTARY RECALL V-085-6)

1. FDA ADVISES THAT:

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PRODUCT: RX VETERINARY INJECTABLE DRUG LABELED AS FOLLOWS:

A. 50 ML. VIAL, STERILE SOLUTION, ECP (ESTRADIAL CYPIONATE),
1. MG. PER ML. FOR VETERINARY USE ONLY. FOR INTRA-MUSCULAR USE
ONLY. EACH ML. CONTAINS: ESTRADIAL CYPIONATE 1 MG. ALSO
CHLOROBUTANOL ANHYDROUS (CHLORAL DERIVATIVE) 5 MG., COTTONSEED
OIL WITH 0.1 PERCENT OXYSTEARIN
916 MG. THE UPJOHN CO., KALAMAZOO, MICHIGAN.

B. 10 ML. VIAL, STERILE SOLUTION, ECP (ESTRADIAL CYPIONATE) 2 MG. PER
ML. FOR VETERINARY USE ONLY. EACH ML. CONTAINS: ESTRADIAL CYPIONATE
2 MG. ALSO CHLORABUTANOL ANYHDROUS 5 MG., COTTONSEED OIL WITH 0.1
PERCENT OXYSTEARIN 9.15 MG. THE UPJOHN CO., KALAMAZOO, MICHIGAN.

EXPIRATION DATE: THE PRODUCT HAS A 5 YEAR EXPIRATION DATE FROM THE
DATE OF MANUFACTURE.

LOT NUMBERS INVOLVED: ALL LOTS OF THE 2 MG/ML, 10 ML. VIALS AND ALL
LOTS OF THE 1 MG/ML, 50 ML. VIALS MANUFACTURED PRIOR TO JANUARY 1974.

MANUFACTURER/RECALLING FIRM:

THE UPJOHN COMPANY
7000 PORTAGE ROAD
KALAMAZOO, MICHIGAN

REASON FOR RECALL: FOLLOWING COMPLAINTS FILED BY VETERINARIANS WITH
THE UPJOHN CO. FROM MARCH 1972 THROUGH JANUARY 1974 INDICATING A
NUMBER OF ADVERSE REACTIONS INVOLVING DOGS, INCLUDING ALTERED BLOOD
CLOTTING, HEMORRHAGE, ENDOMETRITIS, METRITIS, AND PYOMETRITIS, THE
FIRM REVISED THE PACKAGE INSERT IN DECEMBER 1973. THE NEW INSERT
PRINTED IN DECEMBER 1973 DELETED INDICATIONS FOR USE IN THE FOLLOWING
ANIMALS - MARES, SOWS, EWES, CATS, AND CHINCHILLAS. THE INSERT
ALSO DELETED THE FOLLOWING INDICATIONS FOR USE IN BITCHES:
ANESTRUS, FALSE PREGNANCY, MISMATING, PYOMETRA.

THE DECEMBER 1973 REVISED INSERT HAS BEEN PACKAGED WITH THE
1 MG/1 ML., 50 ML. VIALS MANUFACTURED SINCE JANUARY 1974. THE FIRM
HAS DISCONTINUED THE MANUFACTURE OF THE 2 MG/ML., PRODUCT, BUT IS
CONTINUING TO DISTRIBUTE THE PRODUCT UNTIL INVENTORY IS DEPLETED.
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THE LAST BATCH OF THE 2 MG/ML. PRODUCT BEING DISTRIBUTED CONTAINS
THE APRIL 1972 INSERT.

VETERINARY SALES REPRESENTATIVES AND DISTRICT MANAGERS WERE NOTIFIED
BY LETTER DATED JANUARY 25, 1974 REGARDING INSERT CHANGES LIMITING
INDICATED USES AND REGARDING EXPANDED WARNING STATEMENTS. THE FIRM
REVISED THEIR CATALOG PAGE PERTAINING TO ECP, IN JUNE 1974, REFLECTING

THE INSERT CHANGES. THE UPJOHN COMPANY MAILED A LETTER DATED OCTOBER 31, 1975, WITH A COPY OF THE REVISED INSERT ON THE BACK OF THE LETTER TO ALL VETERINARY CUSTOMERS EXPLAINING THE INSERT CHANGES. THE FIRM IS NOT, REPEAT NOT, PHYSICALLY RECALLING THE PRODUCT FROM THE MARKET.

POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES ARE FAMILIAR WITH THE PROBLEMS ASSOCIATED WITH ECP AND THE PACKAGE INSERT REVISIONS. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE UPJOHN COMPANY.

2. FOREIGN CONSIGNEES AS FOLLOWS:

ECP 1 MG/ML. ECP 2 MG/ML.
(50 ML. VIAL) (10 ML. VIAL)
PRODUCT NO. SN7742 PRODUCT NO.
SN7743W

UPJOHN PTY LIMITED 600 VIALS 2000 VIALS
P.O. BOX 138
PARRAMATA, N.S.W., AUSTRALIA
55-73 KIRBY STREET
RYDALMERE, N.S.W. AUSTRALIA

UPJOHN SA. 4200 VIALS 2500 VIALS
PUURS, BELGIUM

UPJOHN SCIENTIFIC OFFICE NONE 2 VIALS
P.O. BOX 866
CAIRO, ARAB REPUBLIC OF EGYPT

UPJOHN OVERSEAS COMPANY 400 VIALS 700 VIALS
HONG KONG P.O. BOX 4324
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AIA BUILDING 10TH FLOOR
NO. 1 STUBBS ROAD
HONG KONG

UPJOHN SCIENTIFIC OFFICE NONE 96 VIALS
P.O. BOX 3100
BAGHDAD, IRAQ

GOVERNMENT AGENCY NONE 5 VIALS
G.M. KHOURY
P.O. BOX 306
AMMAN JORDAN

IHSAN JARRA NONE 5 VIALS
CXO AL-MOJIL DRUG EST.

P.O. BOX SAFAT 2761
KUWAIT, ARABIAN GULF

UPJOHN LIMITED 300 VIALS NONE
P.O. BOX 246
44 MONTEER ROAD
ISANDO, TVL., SOUTH AFRICA KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
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Draft Date: 31 JAN 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
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Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Drafter: DHEW/FDA:JRWEINROTH, M.D.:AMS
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04 MAY 2006

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To: CANBERRA MULTIPLE
Type: TE
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